

REMARKS

Reconsideration of the Final Office Action of April 21, 2003 respectfully is requested. This Amendment is in response to that Final Office Action.

I. Discussion of the Claims

Claims 1-28 and 35-40 are pending in this application. None of the claims have been amended, but in the interest of having a clean set of claims, the listing of claims is included in this Response.

II. General Observations

It appears that there are some fundamental different interpretations of terms/phrases used in the claims between what the Applicants understand the terms/phrases to mean and how the Examiner is interpreting those claims. Largely these terms/phrases are used throughout the application including the claims.

The first term/phrase that appears to be a point of divergence is the phrase "a score for at least one indicator" or "at least one indicator score." The score is based on an accumulation of numerical values for answers to questions asked of the user. Each question has a set of answers with each answer having a numerical value assigned to it as illustrated, for example, in Figures 5-8. When a question is asked that is connected to a particular indicator, then the score for that indicator is increased by the numerical value of the answer given by the user. Sometimes, a question is connected to multiple indicators, in this case then the score for each of the multiple indicators is increased by the numerical value of the answer given by the user.

The second term/phrase is the phrase "at least one indicator level." The indicator level is determined using a scale that has indicator levels assigned to different indicator scores as illustrated in Figures 5-8 and discussed in paragraphs 76-79,¹ for example. If the score for the asthma severity score is 5, then the indicator level would be mild persistent asthma. Paragraph 76. In the embodiment (for example, claims 8 and 37) where the user is able to adjust the indicator level, the user could change "mild persistent asthma" to "mild intermittent asthma" or "moderate persistent asthma." This

adjustment occurs after the indicator score has been changed to the indicator level after the questions have been asked.

The third term/phrase is the term "assessment," which is provided context in the present specification with the following quotation:

the questions asked in the assessment are asked in a randomized order to prevent pattern recognition by the user. By randomizing the questions, the assessment may be utilized during each visit to the doctor by the patient or even at regular intervals by the patient at home, who would then forward the results to the doctor or other healthcare provider.

Paragraph 60. The paragraphs that follow this quotation then provide a series of exemplary questions that could be asked during the assessment. The exemplary questions are of the type that is typically classified as subjective based questions.

III. 35 U.S.C. §102(e) rejection

Claims 1, 4-8, 10, 12-18, and 20-28 have been rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Finkelstein (U.S. Patent No. 6,283,923). Applicants respectfully traverse this rejection.

35 U.S.C. §102 by its language requires that each and every element of a claim be present in a single cited reference to properly have that reference anticipate that claim. See *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1992), citing *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988), *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984); *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 24 USPQ2d 1321, 1326 (Fed. Cir. 1992), *Elmer v. ICC Fabricating Inc.*, 67 F.3d 1571, 36 USPQ2d 1417, 1419 (Fed. Cir. 1995).

a. Claims 1, 4, and 5

Claims 1, 4, and 5 use means-plus-function language to recite the elements that are included within "a system for scoring an asthma survey for a patient based on information entered by a user regarding the patient." Claim 1. Means-plus-function

¹ Reference to paragraph numbers will be to the numbering used in the published patent application (US 2001/0055750 A1).

language is examined to encompass the “broadest reasonable interpretation” within the constraints of 35 U.S.C. §112, sixth paragraph. See *In re Donaldson Co., Inc.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845 (Fed. Cir. 1994)(in banc). The U.S. Patent & Trademark Office “may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination. *Id.*; *In re Graves*, 69 F.3d 1147, 36 USPQ2d 1550 (Fed. Cir. 1997).

Claim 1 recites a “means for questioning the user regarding the patient” that the specification discloses as including asking a series (or set) of questions of the user regarding the patient during one setting. See, e.g., published specification paragraphs 60-73, Figures 5-8. Paragraph 60 further states that “the assessment may be utilized during each visit to the doctor . . . or even at regular intervals by the patient at home.” This would imply that the assessment is completed during one setting. The Final Office Action makes reference to published paragraphs 14 and 15² for using the phrase “repeating the questions asked;” however, this is incorrect since both paragraphs state that a set of steps is repeated for each question of an assessment and parallel the language recited in original claims 6 and 16. Given the statements in paragraph 60, Applicants are unsure of why there would be a belief that the assessment would be stopped and started again with questions being repeated.

Claim 1 also recites a “means for accumulating a **score** for at least one indicator **based on answers** entered by the user to the **questions**” (emphasis added) as discussed, for example, in connection with step 840 in paragraph 54 and illustrated by the score blocks in Figures 5-8. Contrary to the first full paragraph on page 10 of the Final Office Action, claim 1 clearly states that the indicator score is based on multiple answers, and therefore it is correct to state that the indicator score is based on multiple criteria or in the case of Finkelstein multiple symptoms.

On the other hand, Finkelstein appears to disclose asking individual questions on a variety of topics as illustrated in region 340 in Figure 3. Finkelstein, col. 8, lines 54-57. Finkelstein goes on to state that “[e]ach answer is graded according to a predetermined scale, usually 0 to 3. For example, wheezing is graded as 0 (none, no

² Since published paragraph 11 is a heading and paragraph 12 does not use the word “repeating.”

wheezing), 1 (mild wheezing), 2 (moderate wheezing), or 3 (severe wheezing)." Col. 8, lines 57-60. The fundamental difference is that Finkelstein discloses setting a textual level to an individual symptom, but not combining answers to a set of conditions to produce a textual level for a set of conditions. Finkelstein's compiling of scores for a particular symptom over a period of days does not anticipate the accumulating means, because the compilation of scores in Finkelstein is for individual symptoms and there is no disclosure of combining symptoms (or answers to multiple questions) to determine, for example, a severity level, compliance level, and performance level based upon a set of answers to a set of questions.

Finkelstein also does not anticipate "means for correlating the accumulated score to at least one indicator level," because in part Finkelstein does not teach or suggest the accumulating means that handles the indicator score and accumulates it in claim 1.

Claim 1 then concludes by reciting a "means for informing the user of the at least one indicator level from said correlating means" and this is discussed, for example, in connection with step 870 in paragraph 55. The Final Office Action cites col. 3, lines 40-43 of Finkelstein to anticipate the informing means; however, this reliance appears to be misplaced since the citation discusses displaying the information remote from the person who entered the information, which in Finkelstein is the patient. On page 10 of the Final Office Action reference is made to columns 8 and 9 of Finkelstein, which further support the concept that the information is displayed remote from the user ("display region 330 is also helpful to the physician" column 8, line 14). Column 4 at lines 41-45, states that "[t]est results are generated ... and disseminated in a timely manner via selectable data links 50 ... to the patient at the remote monitoring station 20." However, Finkelstein uses "test results" to refer to physical test data such as FVC data. See col. 5, lines 24-26;³ col. 9, lines 44-51. Displaying symptom diary information remote from the patient who is the user is unable to anticipate the recited "means for informing the user."

For these reasons, Applicants respectfully submit that claim 1 is patentable over Finkelstein, because Finkelstein does not disclose each and every element of claim 1.

³ This citation distinguishes between symptom diary data and self-test data (or test data). *Id.*

With respect to claims 4 and 5, Applicants respectfully submit that dependent claims, by definition, include all the limitations of the claims from which they depend, and thus cannot be anticipated if a parent claim is not. See 35 U.S.C. §112(4).

b. Claims 6-8, 10, and 12-15

Claim 6 recites that for each question in an assessment, a series of steps is performed including "incrementing a score for at least one indicator based on the answer to the question." Finkelstein discloses grading the answer to a symptom diary question against a scale (col. 8, lines 53-60), and does not disclose the incrementing step as there is no reason to perform such a step in the Finkelstein invention since each symptom diary question is graded individually thus there is no need to increment a indicator score based on the answer to a question as recited in claim 6.

In the Final Office Action there is reference made to trendpft 534 (trend analysis routine) for teaching incrementing scores. Included in the microfiche portion of Finkelstein is the code for this routine. Cols. 175-198. Cols. 177-178 show that the variables that are available for trend analysis include FVC (Forced Vital Capacity), FEV1 (Forced Expiratory Volume), and FEF25-27% (Forced Mid-Expiratory Flow) all of which are physical data measurements recorded by medical equipment and thus are not subjected to being incremented as part of an indicator score to determine an indicator level. Trend analysis is used to examine medical test data not for subjective data like that contained in the symptom diary in Finkelstein, which based upon the Examiner Interview is what Applicants understand is the portion of Finkelstein being used to make these rejections.

Finkelstein also does not anticipate "correlating each of the at least one indicator score to a corresponding at least one indicator level," because in part Finkelstein does not teach or suggest the indicator score incremented in claim 6.

Claim 7 depends from claim 6 and further recites "informing the user of the at least one indicator level." The relied upon portion of Finkelstein discloses only that the information is provided to someone remote from the user, i.e., the patient, and thus the patient is not informed of rating of his/her answers to diary questions. Col. 3, lines 17-

20, 41-43 ("displaying the test results, response message and patient information at a remotely located diagnosis/evaluation station").

Claim 8 recites "allowing the user to adjust at least one indicator level by at least one level." The relied upon dynamically modified alert conditions of Finkelstein appears to be misplaced, since the "[a]lert parameters can be preset for any of the twenty-nine FVC test parameters." Col. 7, lines 7-14. The Finkelstein alert parameters relate to alerting a medical professional of a problem based upon real physical test data obtained from a FVC test, not answers to symptom diary questions, which disclosure is relied upon in rejecting the claims from which claim 8 depends. Furthermore, the user who has entered the symptom data and been subject to the physical tests does not have the ability to change the threshold for the alert as this is done by someone else, which in Finkelstein is the physician who is not the user as that term is used in claim 1. Additionally, the alert parameters in Finkelstein are set in advance to cause a warning to be issued if the alert is triggered, which is the opposite of the recitation of claim 8 that allows for the indicator level to be changed after the assessment is completed.

Based upon the above, Applicants respectfully submit that claims 6-8 are patentable over Finkelstein, because Finkelstein does not disclose each and every element of each of these claims. Applicants respectfully submit that dependent claims 7, 8, 10, and 12-15, by definition, include all the limitations of the claims from which they depend, and thus cannot be anticipated if a parent claim is not. See 35 U.S.C. §112(4).

c. Claims 16-18 and 20-26

Claim 16 recites "repeating steps a through c [asking a question, receiving an answer, and accumulating a score] for each question in a series of questions that make up the assessment." Claim 16 also recites that "for each of the at least one indicator, there is at least answers to two questions that will result in the indicator." During the interview, the Examiner indicated he understood Finkelstein to teach the accumulation of several days worth of answers to individual symptom diary questions, with each answer having its on rating as discussed in col. 8, lines 53-60 and illustrated as region 340 in Figure 3. Finkelstein, however, does not teach the combining of answers to different questions to come up with a grade according to a predetermined scale.

Applicants respectfully direct the Examiner's attention to the wherein clause that recites "there is at least answers to two questions that will result in indicator" and this is "for each of the at least one indicator," which Applicants submit supports the proposition of combining answers to different questions for each indicator score, which then is used to determine the indicator level. Therefore, Finkelstein is unable to anticipate claim 16. Applicants respectfully submit that dependent claims 17, 18, and 20-26 are also patentable, because, by definition, they each include all the limitations of the claims from which they depend, and thus cannot be anticipated if a parent claim is not. See 35 U.S.C. §112(4).

IV. 35 U.S.C. §103(a) rejections

a. Claims 9 and 19

Claims 9 and 19 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Finkelstein. Applicants respectfully traverse this rejection.

Claim 9 recites that "the at least one indicator includes at least one of a severity level, a compliance level, and a performance level." Claim 9 depends from claim 7 which in turn depends from claim 6 which recites that an answer to a particular question increments a score for at least one indicator. Finkelstein discloses classifying a peak expiratory flow test result per guidelines established by the National Heart, Lung, and Blood Institute. Col. 6, lines 16-20. The peak expiratory flow test is a test to determine a physical characteristic of the patient, and does not include the patient answering any questions. The classification in Finkelstein is based upon a physical characteristic and not a series of answers to multiple questions as recited in Applicants' claims. The communication provided by the physician relates to the physician analysis of physical test results, and not entries made by the patient in response to the symptom diary questions. Col. 7, lines 21-37. The Office Action fails to offer an explanation as to why one of ordinary skill in the art would take this teaching and apply it to scoring answers to questions about a patient to produce at least one indicator level. Therefore, Applicants respectfully submit that claim 9 is patentable over Finkelstein.

Claim 19 recites "personalizing the assessment questions based on the at least one answer received for each of the at least one background information question."

The personalization could be like including the person's name in the assessment question, not the personalization discussed in paragraph 23 on page 6 of the Final Office Action, which discusses alert status and other concepts which appear to have nothing to do with the recitation of claim 19.

Applicants respectfully submit that claims 9 and 19 are patentable over Finkelstein in view of their dependence from claims submitted to be patentable over Finkelstein. See 35 U.S.C. §112(4). Applicants respectfully request that this rejection being withdrawn.

b. Claims 2 and 3

Claims 2 and 3 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Finkelstein in view of Brown (U.S. Patent No. 5,879,163). Applicants respectfully traverse this rejection.

As discussed above, Applicants respectfully submit that claim 1 is patentable over Finkelstein. Applicants respectfully submit that Brown '163 does not teach or suggest the recited means-plus-function in claim 1. Therefore, the combination of Finkelstein and Brown '163 would be unable to teach or suggest claim 1. The recited accumulating means in claim 2 accumulates an indicator score for each of at least two indicators, which is more than collecting answers to questions as discussed in Brown '163 at col. 4, lines 53-64. Claims 2 and 3 depend from claim 1, and therefore are submitted to also be patentable over the combination of Finkelstein and Brown '163. See 35 U.S.C. §112(4).

Additionally, as discussed above in connection to claim 9, Finkelstein does not teach or suggest that the "indicators include severity level, compliance level, and performance level" as recited in claim 3.

Claims 2 and 3 also clearly recite that there are at least two indicators being tracked, i.e., having scores accumulated for each based on answers to questions. This concept is not taught or suggested by Finkelstein.

Applicants respectfully request that this rejection be withdrawn for the above reasons.

c. Claims 11 and 35-40

Claims 11 and 35-40 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Finkelstein in view of Brown (U.S. Patent No. 6,375,469). Applicants respectfully traverse this rejection.

Applicants respectfully submit that claim 11 is patentable over this combination in view of its dependency from patentable claim 6 through claims 7 and 10, because Brown '469 does not rectify the missing teachings of Finkelstein.

Claims 35-40 recite a method for assessing the severity of asthma for a patient. The method includes "asking a plurality of questions", "for each answer to one of said questions, adjusting the score for at least one indicator where said indicator is predetermined to relate to the question for which the answer was provided", "determining an indicator level for each indicator based on comparing that indicator to a predetermined scale", and "providing the indicator level for each indicator". Paragraph 29 of the Final Office Action is silent regarding these elements and as such has failed to set forth a proper rejection of claims 35-40.

The one step that is partially discussed in the Final Office Action is "setting a score for at least two indicators to zero." The alert parameters in Finkelstein are set for 29 FVC parameters, which as has been discussed above are physical measurements that are recorded by medical equipment and are not answers to questions. Therefore, alert parameters are not indicators, which as recited in claim 35 are tied to predetermined questions so that answers from those questions increase the indicator score. The entry of physical measurements in Finkelstein does not change the threshold for the alert levels as those are fixed in advance of the test by the physician.

Brown '469 does not use the phrase "performance level," consequently Applicants are unsure of what is being referred to paragraph 29 of the Final Office Action. Brown '469 teaches determining "[t]he patient's criticality measures the patient's compliance with the treatment regimen." Col. 2, lines 64-65. Criticality includes "a criticality index that measures differences between actual health parameters of the patient ... and corresponding recommended health parameters of the patient ..." Col. 6, lines 45-49. The health parameters include medical history data. Col. 6, lines 37-40.

Consequently, Brown '469 teaches at best just one indicator; however, that indicator is not based upon answers to questions that add to an indicator score but instead are differences between actual status of the patient and an ideal treatment status for the patient.

Thus, neither Finkelstein nor Brown '469 teach multiple indicators let alone indicators that each have a score based on answers to multiple questions that than are compared to predetermined scale to determine the indicator level. The rationale ("the patient may use independently to determine how to better manage their health condition") for combining Finkelstein and Brown '469 are contrary to the disclosed systems/methods of these two patents since both disclosure make it clear that a physician is an active participant from, for example, monitoring in Finkelstein to setting up the treatment plan in Brown '469.

Finkelstein is unable to teach or suggest claim 37 based on the alert parameter, because an alert parameter in Finkelstein is tied to a threshold for either a current reading or a change (col. 7, lines 8-10), thus there is no predetermined scale as recited in claim 37 to allow the user to change the indicator level along. Additionally, the alert parameters in Finkelstein are set in advance to cause a warning to be issued if the alert is triggered, which is the opposite of the recitation of claim 37 that allows for the indicator level to be changed after the assessment is completed.

Applicants respectfully submit that claim 35 is patentable over the alleged combination of Finkelstein and Brown '469. Applicants also respectfully submit that dependent claims 36-40, by definition, include all the limitations of the claims from which they depend, and thus cannot be anticipated if a parent claim is not. See 35 U.S.C. §112(4).

Applicants respectfully request that this rejection be withdrawn.

V. Conclusion

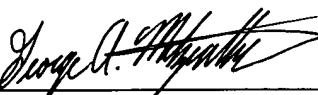
In view of the above amendments and Remarks, it courteously is urged that all the claims are allowable and that the application now is in condition for allowance. If the Examiner believes that the prosecution could be advanced through a telephone

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conversation, then the Examiner is invited to telephone the undersigned. Favorable action in this regard earnestly is solicited.

Respectfully submitted,
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